



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2011-0758; FRL-9363-3]

Sulfentrazone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of sulfentrazone in or on succulent soybeans. Interregional Research Project Number 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA). In addition, this regulation corrects an incorrect commodity definition in the table. The term “Berry, low growing, group 13-07” is being revised to its correct term “Berry and small fruit, group 13-07.”

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2011-0758, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the

Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Andrew Ertman, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9367; email address: ertman.andrew@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2011-0758 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any CBI) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-0758, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 25, 2012 (77 FR 43562) (FRL-9353-6), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E8020) by IR-4, 500 College Road East, Suite 201W., Princeton, NJ 08540. The petition requested that 40 CFR 180.498 be amended by establishing tolerances for residues of the herbicide sulfentrazone (*N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl]-methanesulfonamide) and its metabolites 3-hydroxymethylsulfentrazone (*N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl]methanesulfonamide) and 3-desmethyl sulfentrazone (*N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl] methanesulfonamide), in or on soybean, vegetable, succulent (Edamame) at 0.15 ppm. That notice referenced a

summary of the petition prepared by FMC, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for sulfentrazone including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with sulfentrazone follows.

In the **Federal Register** of July 12, 2012 (77 FR 41081) (FRL-9353-8), EPA published a final rule establishing tolerances for residues of herbicide sulfentrazone in § 180.498(a)(2) in or on rhubarb; turnip roots; turnip tops; sunflower subgroup 20B; citrus fruit group 10-10; low growing berry group 13-07; tree nut group 14; pistachio; and § 180.498 (c) tolerances with regional registrations for wheat forage; wheat hay; wheat grain; wheat straw; and cowpea, succulent. The human health risk assessment used to support this final rule (“Sulfentrazone: Human-Health Risk Assessment for the Establishment of Sulfentrazone Tolerances in/on: Rhubarb, Turnip Roots and Tops, Sunflower Subgroup 20B, Succulent Cowpea, Succulent Lima Bean, Succulent Vegetable Soybean, Wheat (Spring), Citrus Fruit Group 10-10, Low-Growing Berry Group 13-07, Tree Nut Group 14, Pistachios, and Crop Group 18 Nongrass Animal Feeds”), assumed that sulfentrazone would be used on succulent soybeans. Therefore the aggregate risks for sulfentrazone for this action are not changed from those discussed in the July 12, 2012 **Federal Register**.

EPA concluded the following: That the acute dietary exposure from food and water to sulfentrazone will occupy 3.2% of the acute population adjusted dose (aPAD) for females 13-49 years old, the population group receiving the greatest exposure; that chronic exposure to sulfentrazone from food and water will utilize 4.2% of the chronic population adjusted dose (cPAD) for children 1-2 years old, the population group receiving the greatest exposure; and that the combined short-term food, water, and residential exposures result in an aggregate margin of exposure (MOE) of 280 for children 1-2 years old, and an aggregate risk index (ARI) of 3.9 for the general U.S. population and adult males. Because EPA’s level of concern for sulfentrazone is an

MOE of 100 or below and/or an ARI of 1 or below, this MOE and ARI are not of concern. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, sulfentrazone is not expected to pose a cancer risk to humans.

Therefore, EPA concluded that there is a reasonable certainty that no harm will result to the general population and to infants and children from aggregate exposure to sulfentrazone residues. Refer to the July 12, 2012 **Federal Register** document, available at <http://www.regulations.gov>, for a detailed discussion of the aggregate risk assessments and determination of safety. EPA relies upon those risk assessments and the findings made in the **Federal Register** document in support of this action.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography (GC)) is available to enforce the tolerance expression. The method has been forwarded for inclusion in the Pesticides Analytical Manual, Volume II. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and

Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for sulfentrazone on succulent soybean.

V. Conclusion

Therefore, a tolerance is established for residues of sulfentrazone, (*N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl]methanesulfonamide) and its metabolites 3-hydroxymethylsulfentrazone (*N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl]methanesulfonamide) and 3-desmethyl sulfentrazone (*N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl]methanesulfonamide), in § 180.498(a)(2) in or on vegetable, soybean, succulent at 0.15 ppm.

Also, EPA is amending the table in § 180.498(a)(2) to correct the description therein of Crop Group 13-07. Under EPA crop group regulations, Crop Group 13-07 is designated as the “Berry and Small Fruit Crop Group,” 40 CFR 180.41(c)(18). Consistent with this regulation, the petitioner requested the “berry and small fruit group 13-07” and provided the appropriate residue field trial data to support a tolerance on this group. EPA published appropriate notice of this request in the **Federal Register**, correctly describing the requested tolerance as being for the “berry and small fruit group 13-07,” in the **Federal Register** of July 6, 2011 (76 FR 39358) (FRL-8875-6). EPA also

correctly identified in the final rule that petitioners had requested a “berry and small fruit group 13-07” and tolerance and EPA disclaimed any intent to modify this proposed tolerance, (77 FR 41082, 41086). Nonetheless, EPA mistakenly directed that paragraph (a)(2) be amended to establish a tolerance for “low growing berry group 13-07.” EPA is amending paragraph (a)(2) to revise “low growing berry group 13-07” with the correct regulatory term, “berry and small fruit group 13-07,” consistent with the petition’s request and the **Federal Register** notice of the petition and EPA’s disposition of the petition in the final rule published in the **Federal Register** of July 12, 2012.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 21, 2012.

Daniel J. Rosenblatt, Acting

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.498 is amended by revising the entry for “Berry, low growing, group 13-07” to read as “Berry and small fruit, group 13-07” and by adding alphabetically the entry “Vegetable, soybean, succulent” to paragraph (a)(2) to read as follows:

§ 180.498 Sulfentrazone; tolerances for residues.

(a) * * *

(2) * * *

Commodity	Parts per million
* * *	* * *
Berry and small fruit, group 13-07	0.15
* * *	* * *
Vegetable, soybean, succulent	0.15
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